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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/360,685	07/26/99	COVACCI	A CHIR-0157

HM22/0214

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EXAMINER	
RUI, P	
ART UNIT	**PAPER NUMBER**
1645	3

DATE MAILED: 02/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/360,685	Covacci et al.
Examiner	**Group Art Unit**
Phuong Bui	1645

☒ Responsive to communication(s) filed on *Jul 26, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *38-65* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *38-65* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/256848 .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Sequence compliance letter

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Office acknowledges the receipt of preliminary amendment A, Paper No. 2, filed July 26, 1999. Claims 38-65 are pending and are examined in the instant application.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

3. Applicant is required to update the status of the priority and continuing applications as applicable in the first line of the specification.

4. The specification is objected to because of the following informalities: the sequences on page 52, line 8 and the sequences bridging pages 49-50 must be identified by SEQ ID NOs.

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

35 U.S.C. 112, second paragraph

6. Claims 42-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Substantially" is a relative term lacking a comparative basis.

By "an effective amount", it is unclear what effect is desired, i.e., effective for what purpose?

Clarification and/or correction are required.

35 U.S.C. 112, first paragraph

6. Claims 42-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims which recite "exhibits substantially no contribution to toxicity", Applicant is invited to point to the page and line number in the specification where support for such recitation can be found.

In claims which specify "five to about fifteen amino acids", fifteen amino acids is taught as a lower limit and not as an upper limit as used here (see p. 14, ln. 25-27). Amending the above phrase to "five to at least fifteen amino acids" would obviate this rejection.

7. Claims 42-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:5, does not reasonably provide enablement for an amino acid sequence which "exhibits substantially no contribution to toxicity", the "prophylactic or therapeutic vaccine", and the method of treating *H. pylori* infection using said vaccine as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant does not teach any five, ten or fifteen amino acids of SEQ ID NO:5 which is effective for use as a vaccine or for treating *H. pylori* infection. The vaccine use implies that the polypeptide would elicit a protective immune response in administered animals when

challenged with wildtype *H. pylori*. The state of the prior art does not teach which polypeptides/proteins are effective for use as a vaccine or for treating patients infected with *H. pylori*. The current state of the art as of the date of this writing indicates that a mucosal adjuvant is required for vaccine efficacy of *H. pylori* component vaccines. Furthermore, even if a five, ten or fifteen amino acids of SEQ ID NO:5 is effective for use as a vaccine or for treating an *H. pylori* infection, Applicant provided no guidance as to which amino acids of SEQ ID NO:5 would be effective, or how one skilled in the art would be able to eliminate inoperable embodiments without excessive burden and undue experimentation. Applicant also does not teach which five, ten or fifteen amino acids of SEQ ID NO:5 "exhibits substantially no contribution to toxicity". It was not known in the prior art at the time the invention was made which region of SEQ ID NO:5 contributes to toxicity. It is unpredictable based upon Applicant's disclosure as to which five, ten or fifteen amino acids of SEQ ID NO:5 would or would not contribute to toxicity. Accordingly, given the lack of working examples, the state of the prior art, and the lack of guidance as to how inoperable embodiments can be eliminated without undue experimentation, Applicant has not enabled the invention as commensurate in scope with the claims.

Prior art rejections

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 38, 39, 42-50 and 54-56 are rejected under 35 U.S.C. 102(a) as being anticipated by Applicant's admitted prior art Cover et al. (Infection and Immunity, Mar 1990, Vol. 58, No. 3, p. 603-610 (U)). On page 2 of the specification, Applicant states that Cover teaches a 128 kDa protein isolated from *H. pylori*, which appears to be identical to Applicant's claimed CAI protein. Cover also teaches that by immunoblotting with human sera, the 128 kDa protein band was recognized in all supernatants with vacuolizing activity (Abstract). The 128 kDa band of Cover is considered by the Office to be a purified protein. The method to make (recombinantly produced) holds little weight in the patentability of the product claims if the products are indistinguishable. The protein of Cover would inherently comprises five, ten or fifteen amino acids of Applicant's SEQ ID NO:5. Accordingly, the claimed invention is anticipated by Cover.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cover et al. (Infection and Immunity, Mar 1990, Vol. 58, No. 3, p. 603-610 (U)). The teachings of Cover have been discussed *supra*. Cover does not teach the inclusion of a pharmaceutically acceptable carrier. However, it was notoriously well known in the prior art to dilute a purified protein (the 128 kDa band of Cover) in an aqueous medium which would be an inherently pharmaceutically acceptable carrier. Furthermore, Cover teaches the immunization of rabbits with *H. pylori*

antigens to obtain antisera to the antigens (p. 604, "Preparation of antisera" section). The inoculum used for immunization would inherently contain a pharmaceutically acceptable carrier. Accordingly, it would have been *prima facie* obvious at the time the invention was made to dilute the purified 128 kDa protein in a pharmaceutically acceptable aqueous medium with a reasonable expectation of success.

Remarks

12. No claims are allowed.

13. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1645, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Patent Examiner
Group Art Unit 1645
February 8, 2000

PHUONG T. BUI
PATENT EXAMINER

Application No.: ~~08/~~ 09/360685

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Applicant should follow the format of the attached sample statement to request that the CRF filed in the parent application be used to create a CRF in this application.

Applicant Must Provide:

☒ An Initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An Initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification. (8 sequences in spec., 7 listed in sequence listing)

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

Sample Statement

Sample Request to Use Computer Readable Form from Another Application

The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

> The computer readable form in this application, 08/100,000, is identical with that filed in Application Number 07/999,999, filed March 1, 1988. In accordance with 37 CFR 1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].